

Appl. No. 09/869,060  
Amendment dated: November 4, 2006  
Reply to OA of: May 4, 2006

### **REMARKS**

Applicant has amended the claims to more particularly define the invention in view of the outstanding Official Action. This amendment is the required submission which is filed with the RCE filed concurrently herewith in response to the outstanding final rejection. Entry of the amendment is therefore in order and most respectfully requested.

The Examiner objects to the claims because the numbering of the claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the application. Applicants note with appreciation the Examiner's correction of renumbering misnumbered claim 36 to claim 37 and claims 37-43 has been renumbered to claims 38-44. Applicants note with further appreciation that the Examiner has corrected the dependency of renumbered claims 38-44 to depend from the kit claims. The undersigned attorney is sorry for the inconvenience caused by the numbering errors.

The rejection of claims 24-43 under 35 U.S.C. 112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention has been carefully considered but is most respectfully traversed in view of the amendments to the claims. All of the amendments are supported by the specification as originally filed as would be appreciated by one of ordinary skill in the art to which the invention pertains. The claims now remaining in the application are claims 24-57. Applicant most respectfully submits that all of the claims now present in the application are in full compliance with 35 USC 112 and are clearly patentable over the references of record.

It is urged in the Official Action that claims 24-25 and 36-37 are indefinite as referring to "haptan moieties thereof" which is vague because it is unclear as to what this term encompasses. This term is believed to be clear in the context of the "polyhaptan" to which it refers. However, the claims have now been amended to reflect the term "a polyhaptan having haptan moieties comprising S-adenosine homocysteine".

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With respect to the previous formulation of the claims as having a broad definition followed by a specific definition, the Applicant would like to point out that the lack of clarity in the quoted decision results from language indicating that the narrower wording might merely be exemplary. In the present case, however, the "such as" wording, or any wording of similar meaning was quite absent from the claim. However, in order to aid clarity and procedural efficiency, the claims have been amended to incorporate the narrower limitations directly into the definitions of the reagent mixtures. The scope of these claims is believed identical to that indicated on page 7 of the PCT application as filed, but has been recited in a unified wording in response to the Examiner's rejection. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

The Examiner notes that three essential components are recited in claim 24, but only two "stable aqueous reagents" are required. It is believed to be evident from the specification as filed, and especially from Examples 8-10, that the term "reagent" used in the present context indicates a "reagent mixture" rather than a single compound. This is evident at least since the reagents are mixtures with water. The term "reagent mixture" has thus been used for clarity throughout the amended claims and therefore there is no inconsistency in two stable reagent mixtures containing more than two components. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

In amending the claims, the level of one or ordinary skill in the art has been taken into consideration and it is believed that such a skilled person would find the claims definite. Accordingly, it is most respectfully requested that this rejection be withdrawn. Applicant most respectfully submits that all of the claims now present in the application are in full compliance with 35 USC 112 and clearly patentable over the references of record.

The rejection of claims 24-30, 32-33, 35-39, 41-42 and 44 under 35 U.S.C. 102(b) as being anticipated by Cockbain et al. has been carefully considered but is most respectfully traversed.

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Applicant wishes to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The Cockbain reference, however, provides no disclosure of the two or three aqueous reagent mixtures recited in all claims, and therefore cannot disclose any method of using such mixtures. Furthermore, Cockbain provides no teaching to indicate that such reagent mixtures could be stable in aqueous solution.

It is a key finding of the present inventors that by formulating a homocysteine assay using particular reagents from the many possible assay methods for homocysteine, the assay may be carried out efficiently by handling only a small number of separate stable solutions. This method can only be provided by formulating appropriate reagents in reagent mixtures wherein certain components may be stored together but others must be maintained in segregation for stability. Such assays are demonstrated clearly by the Examples of the present application but are in no way taught towards by Cockbain, since questions of component compatibility and the formulation of reagent mixtures for efficient assays are not considered.

In the amended claims, the presence of adenosine or an adenosine analogue is now recited as an essential feature. This provides a minimum of four essential components to be included in a maximum of three reagent mixtures. As a result, the question of compatibility between these components is an essential one. Only the work of the present inventors has provided the understanding of which of these components will form stable and unstable reagent mixtures with each other and therefore these

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reagent mixtures cannot be anticipated. Since all of the independent claims incorporate this essential feature, all claims are believed novel. Accordingly, it is most respectfully requested that the anticipation rejection be withdrawn.

The rejection of claims 34 and 43 under 35 U.S.C. 103(a) as being unpatentable over Cockbain in view of Kuroda et al. has been carefully considered but is most respectfully traversed in view of the above comments and the amendments to the claims.

Kuroda does not, however, relate to homocysteine assays and cannot supply the essential teaching regarding reagent selection and compatibility which is needed to reach the presently claimed reagents or methods for homocysteine analysis. The necessary teaching to overcome the deficiencies in the prior art as discussed above are not present in the Kuroda reference. All claims are therefore believed patentable over this combination of references and the rejection should be withdrawn.

The rejection of claims 31 to 40 under 35 U.S.C. 103(a) as being unpatentable over Cockbain in view of Baylink et al. has been carefully considered but is most respectfully traversed in view of the above comments.

It is notable again, however, that Baylink provides no teaching in the area of homocysteine analysis and cannot supply the missing teaching to render any of the present claims obvious over Cockbain.

In response to the Applicant's previous submissions, the Examiner indicates that Cockbain teaches the *reagents* claimed in the present application. It is believed that this situation is clarified in the amended claims, which now specifically refer to *reagent mixtures* thus indicating that it is the specific arrangement of components in the particular solutions which allows for their stability and effectiveness. These reagent mixtures are believed clearly distinct from the teaching of Cockbain.

The Examiner additionally indicates that in an assay method, patentable weight should not be given to the reagents. The Applicant would submit, however, that the reagents used form the very heart of an assay method and without a suitable combination of reagents and physical manipulations, no assay could be carried out. In

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the amended claims, that specific combination of reagent mixtures and manipulative steps is now explicitly claimed.

In view of the above comments and further amendments to the claims favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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